

---

**AMENDMENTS TO THE CLAIMS**

The following listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of the Claims:**

1. (Currently Amended) A medical device (~~502, 250, 150, 600~~), comprising:
  - a lower surface adapted for application towards the skin of a subject,
  - attaching means (~~571, 272, 161~~) for securing the lower surface relative to the skin,
  - a transcutaneous device adapted to penetrate the skin of the subject,
  - the transcutaneous device being mounted for movement between an extended position in which the transcutaneous device projects relative to the lower surface and a retracted position in which the transcutaneous device is retracted relative to the lower surface,
  - release means (~~550, 275, 162~~) operatable from a first state through an intermediate state to a second state,
  - whereby operation of the release means from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second state causes release of the attaching means.
  
2. (Currently Amended) A medical device as ~~defined~~ in claim 1, wherein
  - the lower surface is a mounting surface (~~570~~) adapted for application on the skin of the subject, the attaching means being adhesive means (~~571~~) provided on the mounting surface for securing the mounting surface to the skin, and
  - wherein the release means (~~550~~) is attached to a peripheral portion of the medical device and comprises a user gripable portion (~~551~~) moveable relative to the mounting surface, the user gripable portion being operatable between a first state through an intermediate state to a second state,
  - whereby operation of the user gripable portion from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the user gripable portion from the intermediate to the second state causes the mounting surface to be pulled off the skin of the subject.

---

3. (Currently Amended) A medical device as ~~defined~~ in claim 2, wherein the release means comprises transcutaneous device retraction means (~~555, 280~~) operatable between a first state in which the transcutaneous device projects relative to the lower surface and a second state in which the transcutaneous device is retracted relative to the lower surface, the transcutaneous device retraction means being moved between its first and second states when the user gripable portion is operated from the first to the intermediate state.

4. (Currently Amended) A medical device as ~~defined~~ in claim 3, wherein:

- the transcutaneous device retraction means is operatable connected to the user gripable portion such that the transcutaneous device retraction means is moved between its first and second states when the user gripable portion is operated from the first to the intermediate state, and wherein
- the medical device is pulled off the skin of the subject when the user gripable portion is operated from its intermediate state to its second state.

5. (Currently Amended) A medical device as ~~defined~~ in claim 3 ~~[[or 4]]~~, wherein the user gripable portion and the transcutaneous device retraction means are operatable connected to each other allowing movement of the user gripable portion to be transferred to the transcutaneous device retraction means.

6. (Currently Amended) A medical device as ~~defined~~ in claim 3, wherein the transcutaneous device retraction means comprises a flexible strip portion (~~555~~) arranged below a portion (~~522~~) of the transcutaneous device, whereby the flexible strip portion will lift the transcutaneous device from the extended position to the retracted position when the user gripable portion is operated from the first to the intermediate state.

7. (Currently Amended) A medical device as ~~defined~~ in claim 2 ~~any of claim 2-6~~, further comprising a flexible sheet member (570, 270) having a lower adhesive surface, the user gripable portion being connected to the sheet member.

8. (Currently Amended) A medical device as ~~defined in any of the previous claims~~ in claim 1, wherein the transcutaneous device is mounted for movement between an initial position in

---

which the transcutaneous device is retracted relative to the lower surface and the extended position in which the transcutaneous device projects relative to the lower surface.

9. (Currently Amended) A medical device as ~~defined~~ in claim 8, comprising locking means ~~(527, 283)~~ for locking the transcutaneous device in the retracted position after a single reciprocation of the transcutaneous device from the initial position to the extended position and to the retracted position.

10. (Currently Amended) A medical device as ~~defined in any of the previous claims~~ in claim 1, wherein the transcutaneous device is a fluid delivery device ~~(531, 651)~~ comprising a distal end adapted to penetrate the skin of the subject and a proximal end ~~(532)~~ adapted to be arranged in fluid communication with a fluid supply.

11. (Currently Amended) A medical device as ~~defined in any of the previous claims~~ in claim 1, further comprising coupling means ~~(511, 161)~~ for releasable securing the transcutaneous device unit to a mating structure, wherein the transcutaneous device is a fluid delivery device comprising a distal end adapted to penetrate the skin of the subject and a proximal end adapted to be arranged in fluid communication with a fluid supply.

12. (Withdrawn - Currently Amended) A medical device as ~~defined in any of the previous claims~~ in claim 1, wherein the transcutaneous device is a fluid delivery device ~~(250)~~, the medical device further comprising:

- a housing ~~(201)~~,
- a reservoir ~~(260)~~ adapted to contain a liquid drug and comprising an outlet means ~~(261)~~ allowing the fluid delivery device to be arranged in fluid communication with an interior of the reservoir, and
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the fluid delivery device.

---

13. (Withdrawn - Currently Amended) A medical device as ~~defined~~ in claim 1, in combination with a pump unit ~~(101)~~ comprising:

- a mounting surface adapted for application against the skin of a subject,
- a reservoir adapted to contain a liquid drug,
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the transcutaneous device,
- wherein the attaching means ~~(141, 161)~~ is adapted for securing the medical device to the pump unit and thereby relative to the skin of the subject, and
- whereby operation of the release means from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second state causes release of medical device from the pump unit.

14. (Withdrawn - Currently Amended) A combination as ~~defined~~ in claim 13, wherein a receiving portion of the pump unit and a corresponding portion of the medical device comprise the attaching means in the form of mating, releasable coupling means ~~(141, 162)~~ allowing the medical unit to be secured to the pump unit.

15. (Withdrawn - Currently Amended) A combination as ~~defined~~ in claim 13, wherein the mounting surface comprises an aperture ~~(121)~~, the transcutaneous device unit being secured relative to the mounting surface with the transcutaneous device in register with the aperture, the transcutaneous device being adapted to extend through the aperture in its extended position.

16. (Withdrawn - Currently Amended) A medical device as ~~defined in any of claims 2-11~~ in claim 1, in combination with a pump unit ~~(405, 505)~~ comprising:

- a reservoir ~~(460)~~ adapted to contain a liquid drug,
- expelling means ~~(470, 482)~~ for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the transcutaneous device,
- wherein the medical device and the pump unit comprise mating coupling means ~~(511, 506)~~ allowing the pump unit to be releasable attached to the medical device.

---

17. (Withdrawn - Currently Amended) A combination as ~~defined in any of claims 13-16 in~~ claim 13, wherein the transcutaneous device is moved from its initial to its extended position when the medical device and the pump unit are attached to each other.

18. (Withdrawn - Currently Amended) A medical ~~(450)~~ device as ~~defined~~ in claim 1, in combination with a pump unit ~~(401)~~ and a base plate unit ~~(490)~~, the base plate unit comprising:

- an upper surface and a lower mounting surface adapted for application against the skin of a subject, the mounting surface comprising mounting means ~~(470)~~ having an adhesive surface, the pump unit comprising:
- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the transcutaneous device to be arranged in fluid communication with an interior of the reservoir,
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the transcutaneous device,
- the pump unit and the base plate unit comprising mating, releasable coupling means ~~(441)~~ allowing the pump unit to be secured to the base plate unit,
- wherein the attaching means ~~(461)~~ is adapted for securing the medical device to the pump unit and/or the base plate unit and thereby relative to the skin of the subject, and
- whereby operation of the release means from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second state causes release of medical device from the pump unit.

19. (Currently Amended) ~~A combination (300, 400) as defined in any of the previous claims~~ A medical device as in claim 1, further comprising a first peelable sheet ~~(371)~~ having an upper surface and an adhesive lower surface, the upper surface being adapted for peelable detachment from a lower mounting surface.

20. (Currently Amended) A medical device ~~or combination~~ as ~~defined~~ in claim 19 ~~[[17]]~~, comprising at least one further peelable sheet ~~(372, 373)~~, each further peelable sheet comprising an upper surface and an adhesive lower surface, the first and the further peelable sheets being arranged in a stacked arrangement with their respective upper surfaces attached to the overlying adhesive surface.

---

21. (Currently Amended) A medical device ~~(502)~~ comprising:

- a mounting surface adapted for application to a skin site,
- an adhesive ~~(571)~~ for securing the mounting surface to the skin site,
- a transcutaneous device ~~(530)~~ adapted to penetrate the skin at the skin site, the transcutaneous device being mounted for movement between an initial position in which the transcutaneous device is retracted relative to the lower surface and an extended position in which the transcutaneous device projects relative to the lower surface, and for movement between the extended position and a retracted position in which the transcutaneous device is retracted relative to the lower surface,
- actuation means ~~(540)~~ comprising a first user gripable portion ~~(541)~~ moveable relative to the mounting surface, the first user gripable portion being moveable to cause the transcutaneous device to be moved from the initial position to the extended position, and a release means ~~(550)~~ attached to a peripheral portion of the medical device and comprising a second user gripable portion ~~(551)~~ moveable relative to the housing, the second user gripable portion being moveable to cause the transcutaneous device to be moved from the extended position to the retracted position, the release member further allowing a pulling force to be applied to the peripheral portion of the medical device to thereby remove the medical device when secured to the skin site,
- wherein in an initial state the first user gripable portion at least partially covers the second user gripable portion, such that the second user gripable portion is exposed when the first user gripable portion is moved to cause the transcutaneous device to be moved from the initial position to the extended position.

22. (Currently Amended) A medical device ~~(502)~~ comprising:

- a mounting surface adapted for application towards a skin site,
- a transcutaneous device ~~(530)~~ adapted to penetrate the skin at the skin site, the transcutaneous device being mounted for movement between an initial position in which the transcutaneous device is retracted relative to the lower surface and an extended position in which the transcutaneous device projects relative to the lower surface, and for movement between the extended position and a retracted position in which the transcutaneous device is retracted relative to the lower surface,
- actuation means ~~(540)~~ comprising a first user actuatable portion being actuatable to cause the transcutaneous device to be moved from the initial position to the extended position, and

---

release means comprising a second user actuatable portion actuatable to cause the transcutaneous device to be moved from the extended position to the retracted position,

- wherein the release means cannot be actuated before the actuation means has been actuated.

23. (Withdrawn - Currently Amended) A medical device as ~~defined~~ in claim 21 [[or 22]], wherein the transcutaneous device is a fluid delivery device (~~250~~), the medical device further comprising:

- a reservoir (~~260~~) adapted to contain a liquid drug and comprising an outlet means (~~261~~) allowing the fluid delivery device to be arranged in fluid communication with an interior of the reservoir, and
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the fluid delivery device.

24. (Currently Amended) A medical device as in claim 1 ~~defined in any of the previous claims~~, wherein the portion (~~531~~) of the transcutaneous device adapted to penetrate the skin of the subject is in the form of a hollow metallic needle comprising an outer smooth coating of a polymeric material.

25. (Original) A medical device comprising:

a mounting surface for mounting the device towards the skin of a user;

a transcutaneous device for penetrating the skin of the user, the transcutaneous device being moveable between an extended position and a retracted position;

a release comprising a user graspable portion, the user graspable portion being moveable to cause the transcutaneous device to be moved from the extended position to the retracted position, the release further being coupled to the medical device in a manner that allows the user to exert a force on the medical device to remove the medical device away from the user's skin after the transcutaneous device has been moved from the extended position to the retracted position.

26. (Original) The device of claim 25, further comprising an adhesive on the mounting surface.

27. (Original) An apparatus comprising:

- a surface,
- a transcutaneous device adapted to penetrate the skin of a subject,
- the transcutaneous device being moveable between an extended position in which the needle projects relative to the surface and a retracted position in which the needle is retracted relative to the surface,
- a coupling for releasably securing the transcutaneous device unit to a mating structure,
- a release operatable from a first state through an intermediate state to a second state,
- wherein operation of the release from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the release from the intermediate to the second state causes release of the coupling.

28. (Withdrawn - Original) An apparatus comprising:

- a pump unit comprising a pump;
- a transcutaneous device unit that is releasably coupleable with the pump unit, the transcutaneous device unit comprising a transcutaneous penetration device for penetrating the skin of a patient when the transcutaneous penetration device is moved from a retracted position to an extended position;
- a mounting surface for mounting the apparatus to the skin of a patient;
- a reservoir for containing a medication to be pumped by the pump thru the transcutaneous penetration device into a patient,
- a release that is moveable from a first position to second position and to a third position, wherein when the release is in the first position, the transcutaneous penetration device is penetrating the skin of a patient, and wherein when the release is in the second position the transcutaneous device is retracted and wherein when the release is moved to the third position, the mounting surface is removed from the skin.

29. (Withdrawn - Original) A method of infusing a medication into a patient, the method comprising the steps of:

- a. temporarily mounting a medication delivery device on a skin surface of a patient,
- b. extending a transcutaneous device from the medication delivery device thru the skin of a patient,



- c. infusing the medication from the medication delivery device into the patient,
- d. retracting the transcutaneous device by exerting a force on a release member, and
- e. removing the medication delivery device from the patient's skin by continuing to exert a force on the release member.

30. (Withdrawn - Original) The method of claim 29, wherein the retracting step (d) and the removing step (e) are done sequentially without a pause between steps.

31. (Withdrawn - Original) The method of claim 29, wherein the mounting step comprises adhering the medication delivery device to the skin surface with an adhesive that is arranged on a surface of the medication delivery device.

32. (Withdrawn - Original) A method of removing a medication delivery device that is adhered to the skin on a patient and a transcutaneous device that is extending thru the skin of a patient, the method comprising the steps of:

- a. exerting force on a release that is coupled to the transcutaneous device to retract the transcutaneous device from the skin on the patient, and
- b. continuing to exert force on the release until the medication delivery device is removed from the skin of the patient.